

Applicant : Jennifer Richardson et al.
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Attorney's Docket No.: 07334-312001

REMARKS

Rejections Under 35 U.S.C. §112, second paragraph

Claims 33, 34 and 59-79 were rejected as indefinite for the use of the phrase "predetermined value" in claim 33. Applicants have amended claim 33 to recite "(d) identifying the test compound as a candidate therapeutic agent for the treatment of prostate cancer if the level of expression of alpha-methylacyl-CoA racemase mRNA in the test sample exposed to the test compound is less than in a control test sample not exposed to the test compound" (emphasis added). Support for this amendment is found at page 45, line 27 to page 46, line 8. No new matter has been added. Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. §112, first paragraph (written description)

Claim 34 and 59-79 were rejected as failing to meet the written description requirement.

The Examiner argued that claims 34, 66-72, 74, 78 and 79 fail to meet the written description requirement because they encompass the use of "sequences of unknown structure and function, provided that they are at least" a certain length "and hybridize under the hybridization conditions recited in claim 34 via a common fragment to SEQ ID NO:3." Applicant has amended claim 34 to specify that the nucleic acid molecule a fragment of the full-length complement of SEQ ID NO:3. Thus, the nucleic acid molecules are defined both by: 1) the ability to hybridize under specific conditions to a specific sequence and 2) the presence of a fragment of at least 15 nucleotides of the full-length complement of a specific sequence. Thus, claim 34 defines the nucleic acid molecule by physical characteristics and the presence of a portion of a defined sequence. This is sufficient to meet the standard set forth in *University of California v. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997). As the Examiner points out, the *Lilly* court held that the written description requirement for a nucleic acid molecule can be met by "a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" The hybridization and sequence limitations in claims 34 amount to a recitation of common structural features. It is Applicants' position that

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the written description requirement has been met for claim 34 and the claims that depend from claim 34.

Regarding claims 59-65, 73 and 75-77, the Examiner argued that the use of term comprising in reference to the nucleic acid probe means that the probe could include "sequences of unknown structure and function that are attached to" a certain number of contiguous nucleotides of SEQ ID NO:3. Claim 59 has been amended to depend from claim 34. Thus, claim 59 includes the limitation that the probe hybridize to a specific sequence under specific hybridization conditions. Thus, while the probe can contain sequences not present in the complement of SEQ ID NO:3, it must still meet the hybridization requirements of claim 34. Thus, claim 59, like claim 34, meets the written description requirement of 35 U.S.C. §112, first paragraph.

Regarding claims 34 and 59, The Examiner argued that the "complement" of SEQ ID NO:3 might be a partial complement that "could share with SEQ ID NO:3 only a few nucleotides". Applicants have amended claims 34 and 59 to recite "the full-length complement of SEQ ID NO:3".

Rejections Under 35 U.S.C. §112, first paragraph (enablement)

Claims 34 and 59-79 were rejected as failing to meet the enablement requirement. The Examiner argued that the claims are not enabled because "Applicant has not taught how to make numerous nucleic acid probes with unknown structure for use in the claimed method." As discussed above, the probes of the present claims are clearly defined and meet the written description requirement. Those skilled in the art know how to make and how to use nucleic acid probes that hybridize under specific conditions to a specific sequence. The design and use of such probes is routine in the art.

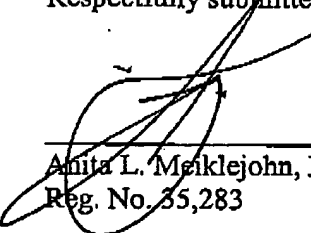
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Conclusion

Applicants believe that the claims are in condition for allowance. Enclosed is a Petition for Extension of Time with authorization to charge fee to the Deposit Account. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 16 MAY 2005

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